

U.S. Patent Appln. S.N. 10/069,145
AMENDMENT AFTER FINAL REJECTION

PATENT

REMARKS

This Amendment rewrites claim 8 and places claim 12 in independent form. The 25 mol-% maximum tetraalkoxysilane feature of claim 8 is supported at page 6, lines 13-15 of the specification as originally filed. Claims 8-13, 15 and 16 are pending.

Entry of this Amendment is earnestly requested, as a Request for Continued Examination is being filed concurrently with this Amendment.

Examiner Sheikh is thanked for indicating the allowability of claims 12, 13, 15 and 16. This Amendment overcomes the objection to those claims by placing claim 12 in independent form. Reconsideration and withdrawal of the objection to claims 12, 13, 15 and 16 are earnestly requested.

Examiner Sheikh is also thanked for the courtesies extended to the undersigned during a telephonic interview held May 27, 2005. The Examiner Interview Summary Record accurately reflects the substance of the interview.

The 35 U.S.C. § 103(a) rejection of claims 8-11 over U.S. Patent No. 5,858,280 to Zhang et al. in view of U.S. Patent No. 5,804,318 to Pinchuk et al. is respectfully traversed. The claimed invention is a biodegradable silica xerogel composition comprising a silica xerogel which is capable of controlled release of a

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biologically active agent. The silica xerogel is derived from a tetraalkoxysilane with part of the tetraalkoxysilane, up to 25 mol-%, being replaced by an alkylsubstituted alkoxy silane.

The cited combination of references fails to raise a *prima facie* case of obviousness against the claimed composition because the cited references fail to disclose, teach or suggest the maximum 25 mol-% alkylsubstituted silane feature of the silica xerogel. In Zhang et al., only examples 10 and 14 disclose any specific amounts of alkylsubstituted silanes. In example 10, it is stated the amount of TEOS (tetraalkoxysilane) is 25 mol-%, thus the amount of alkylsubstituted silane [methyltriethoxysilane (MTES)] is 75 mol-%. (Col. 8, lines 13-15). In example 14, the amounts of TEOS and MTES in the composition can be calculated from the starting materials and the sentence: "The film consists of 20 mole % of SiO₂ and 80 mole % of CH₃SiO_{1.5}" (Col. 9, lines 26-27). The calculation produces the following results: 30 mol-% of TEOS and 70 mol-% MTES. One of ordinary skill in the art is given no motivation or disclosure to reduce the amount of alkylsubstituted alkoxy silane from 75 mole-% or 70 mole-% down to 25 mole-% or less.

Pinchuk et al. also fails to disclose or suggest that an anti-thromogenic agent such as heparin can be encapsulated into sol-gel derived xerogel derived from tetraalkoxysilane which has been co-

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hydrolyzed with up to 25 mol-% of an alkylsubstituted alkoxy silane, or that heparin may be controllably released from the xerogel. Instead, Pinchuk et al. discloses a surface coating comprising a non-silica hydrogel containing pendant primary and tertiary amine groups (Col. 3, lines 26-29).

Pinchuk et al. is cited to show an epoxy-functionalized silane primed catheter dipped into a hydrogel solution containing 2% heparin. However, the silane coupling agent is used only for silylation of the surface of the material to be coated. The coating itself is not made of sol-gel derived silica xerogel derived from tetraalkoxysilane. Pinchuk et al. expressly teaches that the anticoagulant agent is bound to quaternary ammonium cations present in its (non-silica) hydrogel. See Col. 3, lines 31-33, Col. 5, lines 13-15 and Fig. 4. There is no teaching or suggestion that heparin may be controllably released from a sol-gel derived silica xerogel derived from tetraalkoxysilane.

One of ordinary skill in the art, seeking a biodegradable silica xerogel composition which is capable of controlled release of heparin, would not be led to the claimed composition by Zhang et al. and Pinchuk et al. Reconsideration and withdrawal of the obviousness rejection of claims 8-11 over Zhang et al. in view of Pinchuk et al. are earnestly requested.

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The 35 U.S.C. § 103(a) rejection of claims 8-11 over Kuncova et al., 60 Collect.Czech.Chem.Comm. 1573 (1995) in view of Pinchuk et al. is respectfully traversed. The inventors have discovered a biodegradable composition comprising a silica xerogel which is capable of controlled release of a biologically active agent. A feature of the claimed biodegradable composition is the partial replacement of a tetraalkoxysilane with up to 25 mol-% of an alkylsubstituted alkoxysilane.

The combination of Kuncova et al. and Pinchuk et al. fails to raise a *prima facie* case of obviousness against the claimed composition. More particularly, Kuncova et al. fails to disclose the partial replacement of a tetraalkoxysilane with up to 25 mol-% of an alkylsubstituted alkoxysilane. Pinchuk et al. merely discloses a non-silica hydrogel bound to a surface to be coated by a silane coupling agent.

Reconsideration and withdrawal of the obviousness rejection of claims 8-11 over Kuncova et al. in view of Pinchuk et al. is respectfully requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 8-11, and issuance of a Notice of Allowance directed to claims 8-13, 15 and 16, are earnestly requested. The Examiner is urged to

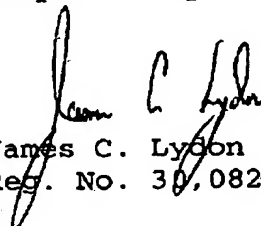
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telephone the undersigned should she believe any further action is required for allowance.

Appropriate fees for a one month Extension of Time and a Request for Continued Examination are attached. It is not believed any additional fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is authorized to charge our Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,



James C. Lydon
Reg. No. 30,082

Atty. Case No.: TUR-125
100 Daingerfield Road, Suite 100
Alexandria, Virginia 22314
Telephone: (703) 838-0445
Facsimile: (703) 838-0447

Enclosures:
Petition for Extension of Time
Request for Continued Examination